General and Plastic Surgery Advisory Committee Panel Meeting on Soft-tissue Fillers

Mathew Avram, MD, JD, President

American Society for Dermatologic Surgery Association (ASDSA)

ASDSA
American Society for Dermatologic Surgery ASSOCIATION

- Fillers are seeing increased patient demand: the 2019 ASDS Procedures Survey showed dermatologic surgeons administered 1.6 million soft-tissue filler injections, up 78% over eight years.

- ASDS convened a multidisciplinary Soft Tissue Fillers Evidence-based Guideline Task Force:
  - 8 board certified dermatologists (ASDSA members)
  - 1 plastic surgeon
  - 1 facial plastic and reconstructive surgeon
  - 1 oculoplastic surgeon
  - 2 patient representatives
  - 1 methodologist
- The ASDS-led Fillers Guideline TF determined that the topic of preventing and treating adverse events of injectable fillers required the development of evidence-based clinical practice guidelines to support decision-making in daily practice.

- Knowledge of vascular anatomy is essential for all filler injectors (Board certified dermatologists/physcians have this education)
- **Intravascular injection is possible at any injection location on the face, but certain locations carry a higher risk.**
- Accidental injection of filler into facial arteries can cause:
  - filler embolization and vascular occlusion, leading to tissue ischemia
  - necrosis
  - visual abnormalities
  - blindness
  - stroke

- Filler adverse events are likely underreported and increasing in frequency as the popularity of injectable fillers grows
- Physician offices are likeliest to report errors
- ASDSA/Northwestern University developed the Cutaneous Procedures Adverse Events Reporting (CAPER) system.
  - Voluntary reporting of adverse events during dermatologic surgery procedures.
  - Data used to help monitor; identify practice and/or education gaps.
  - Identify any potential risk factors for adverse events.
  - More information at www.caper.net.

The TF addressed the eight following strategies to reduce injection-related visual compromise:

1. **Obtain informed consent from the patient regarding the rare possibility of IRVC, which can have life-altering consequences.**
2. Develop and post an IVRC protocol, review it with team members, and always have ample hyaluronidase on hand.
3. Stop injecting at first sign of visual compromise, which usually occurs during or immediately after injection and is most often unilateral. Half of the patients show skin involvement, ophthalmoplegia, or ptosis, of which most resolve. Headache, nausea, and vomiting may or may not be present.

4. Conduct evaluation of immediate post event visual status BEFORE any intervention. **The importance of this cannot be overstated.**
5. Document visual acuity in each eye separately and note in chart.
6. Keep patient informed of evolving events, notify family member, and accompany both through entire process.

Original Article

Preventing and Treating Adverse Events of Injectable Fillers: Evidence-Based Recommendations From the American Society for Dermatologic Surgery Multidisciplinary Task Force

Derek H. Jones, MD,* Rebecca Fitzgerald, MD,† Sue Ellen Cox, MD,† Kimberly Butterwick, MD,§ W. Hassen Murad, MD,‖ Shannon Humohrey, MD,¶ Jean Carruthers, MD,** Steven H. Dayan, MD,†† Lisa Donofrio, MD,‡‡ Nowell Solish, MD,§§ G. Jackie Yee, MD,‖‖ and Murad Alam, MD¶¶

All injectable fillers may be associated with common injection site reactions such as redness, swelling, bruising, and tenderness, which usually resolve within 1 to 2 weeks. Rare but more serious adverse events from injectable fillers include vascular occlusion leading to skin necrosis or blindness, inflammatory events, and nodule formation, among others.[1] Although rare, they are likely underreported and increasing in frequency as the popularity of injectable fillers grows. Such adverse events can be distressing to both patient and physician and present therapeutic and potential legal challenges.[2] The American Society for Dermatologic Surgery (ASDS) has determined that the topic of preventing and treating these adverse events of injectable fillers requires the development of evidence-based clinical practice guidelines to support decision-making in daily practice.

From the *Skin Care and Laser Physicians of Beverly Hills, Los Angeles, California; †Private Practice, Los Angeles, California; ‡Aesthetic Solutions, Assoc Clinical Faculty, UNC Department of Dermatology, Consulting Associate, Duke University Department Dermatology, Chapel Hill, North Carolina; §Cosmetic Laser Dermatology, San Diego, California; ‖Evidence-based Practice Center, Mayo Clinic, Rochester, Minnesota; ¶Department of Dermatology and Skin Science, University of British Columbia, Vancouver, Canada; **Department of Ophthalmology and Visual Sciences, University of British Columbia, Vancouver, Canada; ††Dennova Research, Clinical Assistant Professor, University of Illinois, Chicago, Illinois; ‡‡Department of Dermatology, Yale University School of Medicine, New Haven, Connecticut; §§Department of Dermatology, University of Toronto, Toronto, Canada; ‖‖Baker Plastic Surgery, Miami, Florida; ¶¶Departments of Dermatology, Otolaryngology, and Surgery, Northwestern University, Chicago, Illinois

D. H. Jones is an Investigator or Consultant for Allergan, Galderma, Merz and Revance. R. Fitzgerald is a Consultant for Allergan, Galderma, and Revance, and a Trainer for Galderma. S. E. Cox is Investigator and/or Consultant for Allergan, Croma, Evolus, Galderma, Merz and Revance. K. Butterwick is an Investigator or Consultant for Allergan, Galderma, Merz, Sinclair, Sunevia, Histogen, Revance, and Evolus. M. H. Murad is a guideline methodologist with partial funding from ASDS to perform this work. S. Humphrey is a Consultant/Investigator/Speaker for Allergan, Galderma, and Revance, a Consultant/Speaker for Merz and L'Oreal, a Consultant for Sinclair Pharma, and an Investigator for Evolus. J. Carruthers is a Consultant and Investigator with Allergan, Alphaeon, Bonti, and Revance, and receives Royalties from Elsevier and UpToDate. S. Dayan is an Investigator or Consultant for Allergan, Galderma, Merz and Revance. L. Donofrio is a Consultant or Investigator for Canfield Scientific, Galderma, Allergan, and Revance. N. Solish is an Investigator or Consultant for Allergan, Galderma, Merz, Croma, and Revance. G.J. Yee is a Consultant for Allergan, Galderma, Revance, and Endo Aesthetics. The remaining author has indicated no significant interest with commercial supporters.

Address correspondence and reprint requests to: Derek H. Jones, MD, Skin Care and Laser Physicians of Beverly Hills, 9201 W. Sunset Boulevard, Suite 602, Los Angeles, CA 90069, or e-mail: derekjonesmd@gmail.com

http://dx.doi.org/10.1097/DSS.0000000000002921

Methods

American Society for Dermatologic Surgery convened a multidisciplinary task force that consisted of ASDS member physician specialists (8 board-certified in dermatology, 2 in plastic and reconstructive surgery, and 1 in oculoplastic surgery), 2 patient representatives, and a methodologist. The committee task force identified a priori 6 critical questions and commissioned the Mayo Clinic Evidence-based Practice Center to conduct systematic reviews to summarize the relevant evidence. These reviews are published separately.[3] The committee used the GRADE approach (Grading of Recommendations, Assessment, Development and Evaluation), which rates the certainty of evidence as high, moderate, low, or very low. Randomized trials start with a high certainty rating that can be lowered based on various factors and observational studies start with a low certainty rating that can be lowered or raised based on various factors.[4] The GRADE approach leads to 2 types of recommendations: (1) strong recommendations (most compelling, to be applied in most situations with minimal variation) that are denoted by the term "recommend," and (2) conditional recommendations (variation in care is acceptable based on the context and patient's values) that are denoted by the term "suggest." The determination of the strength of recommendation is based on the certainty of evidence, balance of benefits and harms, patient's values, resources, acceptability, and feasibility.[4]

Prevention of Vascular Occlusion, Blindness, and Stroke

Background

Accidental injection of filler into facial arteries can cause filler embolization and vascular occlusion, leading to tissue ischemia, necrosis, visual abnormalities, blindness, and stroke. Knowledge of vascular anatomy is essential for all filler injectors. Intravascular injection is possible at any injection location on the face, but certain locations carry a higher risk.

Recommendations

Although there is no absolutely risk-free injection protocol, ASDS Task Force recommends the following strategies to reduce the risk of vascular occlusion with injectable fillers (Strong recommendation, Moderate certainty evidence):

ASDSA American Society for Dermatologic Surgery ASSOCIATION

DERMATOLOGIC SURGERY

7. In patients with signs or symptoms (s/s) of central nervous system (CNS) involvement, contact your local hospital's emergency stroke service and call 911 for immediate transport to the emergency room. In the absence of s/s, evaluate and image the patient to rule out CNS involvement once the ocular event has been addressed. *Time is of the essence. Immediately contact an eye expert who is familiar with this risk and its management. A preexisting relationship with an oculoplastic surgeon, ophthalmologist, and/or retina specialist can avoid unnecessary delays.*

8. Hyaluronidase injections are quick, safe, and easily done at the bedside, and should be considered immediately. Inject .150 units hyaluronidase into the treated area, all areas of skin ischemia, and along the path of arteries leading to the eye. Similar doses can be injected adjacent to and in the supraorbital and supratrochlear foramina. Repeat in quick succession as needed. Retrobulbar (RBH) and peribulbar (PBH) injections may be beneficial, but this remains controversial at this time. {Keep detailed notes of events, interventions, and timing, and all interactions with patient, family, specialists, and facilities. Inform the product manufacturer of the incident for FDA reporting.}

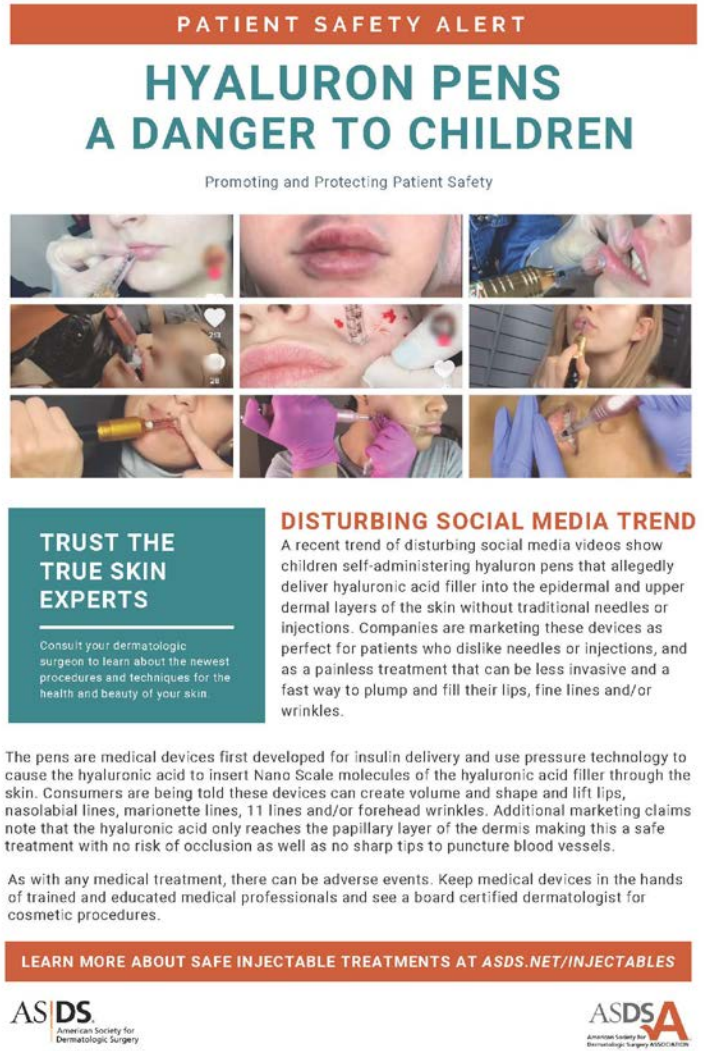
COVID-19 Vaccines & Fillers

- ASDS reviewed FDA safety data from the Moderna vaccine trial
- Three participants out of 15,184 patients who received at least one dose of mRNA-1273 developed facial or lip swelling presumed to be related to dermal filler placement.
- All events resolved after treatment
- Physcians most likely to report complications

ASDSA
American Society for Dermatologic Surgery ASSOCIATION

ASDSA Alert: Hyaluron Pens Danger

- ASDSA reported to the FDA the disturbing trend regarding children/public buying and using “hyaluron pens” to inject hyaluronic acid filler into the epidermal and upper dermal layers of the skin.
- Board certified dermatologists have seen social media where children use these pens to self-inject and promote their use to peers.



PATIENT SAFETY ALERT

HYALURON PENS
A DANGER TO CHILDREN

Promoting and Protecting Patient Safety

TRUST THE TRUE SKIN EXPERTS

Consult your dermatologic surgeon to learn about the newest procedures and techniques for the health and beauty of your skin.

DISTURBING SOCIAL MEDIA TREND

A recent trend of disturbing social media videos show children self-administering hyaluron pens that allegedly deliver hyaluronic acid filler into the epidermal and upper dermal layers of the skin without traditional needles or injections. Companies are marketing these devices as perfect for patients who dislike needles or injections, and as a painless treatment that can be less invasive and a fast way to plump and fill their lips, fine lines and/or wrinkles.

The pens are medical devices first developed for insulin delivery and use pressure technology to cause the hyaluronic acid to insert Nano Scale molecules of the hyaluronic acid filler through the skin. Consumers are being told these devices can create volume and shape and lift lips, nasolabial lines, marionette lines, 11 lines and/or forehead wrinkles. Additional marketing claims note that the hyaluronic acid only reaches the papillary layer of the dermis making this a safe treatment with no risk of occlusion as well as no sharp tips to puncture blood vessels.

As with any medical treatment, there can be adverse events. Keep medical devices in the hands of trained and educated medical professionals and see a board certified dermatologist for cosmetic procedures.

LEARN MORE ABOUT SAFE INJECTABLE TREATMENTS AT *ASDS.NET/INJECTABLES*

ASDS American Society for Dermatologic Surgery

ASDSA

ASDSA pledges its help to the FDA in making sure fillers are safely given to patients and stay in the hands of physicians who can properly supervise other medical personnel

We respectfully ask the FDA consider renaming this panel: "General, Plastic and **Dermatologic** Surgery Advisory Committee" to reflect board certified dermatologists' contributions and expertise in these areas

Thank you

Questions can be directed to *advocacy@asds.net*